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APPLICATION NUMBER	FILED DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/118,730	07/17/98	BEAVERS	E : 281-28
			EXAMINER

HM12/0315

WILLIAM H EILBERG  
820 HOMESTEAD ROAD  
PO BOX 7  
JENKINTOWN PA 19046

WHI UNIT	PAPER NUMBER
	4

1623

DATE MAILED: 03/15/99

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on \_\_\_\_\_
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- ☒ Claim(s) 1-23 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-23 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

—SEE OFFICE ACTION ON THE FOLLOWING PAGES—

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz et al (US Patent No. 4,808,576).

Applicants set forth product-by-process claims of a free-acid form of hyaluronic acid made by a method which involves obtaining the free acid form of hyaluronic acid from an alkali-metal salt of hyaluronic acid.

The free acid form of hyaluronic acid is well-known in the art as indicated in the Schultz et al patent which discloses hyaluronic acid as being useful in the treatment of irritated or inflamed tissue by remote application wherein the hyaluronic acid may be used in its free acid form (see column 4, lines 5-19). While Applicants's claims are directed to a product limited by the process employed in its production there is no reason found for concluding that the product claimed (e.g., free acid form of hyaluronic acid) could be distinguished from the free acid form of hyaluronic acid of the Schultz et al's patent merely because the claimed product was produced under the specific conditions recited, which conditions fall within the purview of the disclosure of the Schultz et al's patent. Accordingly, it would have been obvious to one of ordinary skill in the art having the Schultz et al patent before him to employ a free acid form of hyaluronic acid of the

instant claims in view of their closely related structures and the resulting expectation of similar therapeutic properties.

Applicants are reminded that process limitations cannot impart patentability to a product which is not patentably distinguished over the prior art. *In re Thorpe et al.* (CAFC 1985), supra; *In re Dike* (CCPA 1968) 394 F2d 584, 157 USPQ 581; *Tri-Wall Containers, Inc. v. United States et al.* (Ct Cls 1969) 408 F2d 748, 161 USPQ 116; *In re Brown et al.* (CCPA 1972) 450 F2d 531, 173 USPQ 685; *Ex parte Edwards et al.* (BPAI 1986) 231 USPQ 981.

3. The De Belder et al patent (US Patent No. 4,886,787) which discloses the use of Hyaluronic acid in free acid form for the preparation of gels (see column 4, lines 49 and 50; the Choay et al patent (US Patent No. 4,168,377) which discloses a process for replacing sodium with calcium in heparin which involves isolating the heparin in its free acid form (see column 1, lines 51-55); and the Omiya patent (US Patent No. 4,508,894) which discloses carboxymethyl cellulose have a free acid form of carboxymethyl groups and process of preparation (see claims 1-11 of the Omiya patent) all can be used to reject the instant claims under 35 U.S.C. 103(a) as being unpatentable over the prior art.

4. All the claims are rejected.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 8:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the primary examiner signing this office action, James O. Wilson, can be reached on (703) 308-4624. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

*E. White*

White

March 8, 1999

*James O. Wilson*  
JAMES O. WILSON  
PRIMARY EXAMINER  
Group 1600